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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,077

06/23/2003

Stephen Suffin

CNSR-09275

1225

23535 7590 09/04/2009

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,077	<b>Applicant(s)</b> SUFFIN, STEPHEN	
	<b>Examiner</b> D L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-42, 50-56 and 61-64 is/are pending in the application.
- 4a) Of the above claim(s) 61-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-42 and 50-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 8/25/09 wherein claims 1-39, 43-49, and 57-60 were canceled and claims 40 and 54 were amended. In addition, the Examiner acknowledges receipt of the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/09 has been entered.

**Note:** Claims 40-42, 50-56, and 61-64 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 8/25/09 to the rejection of claims 40-42 and 50-56 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in part for the reasons set forth below.

### **112 First Paragraph Rejection**

The 112, first paragraph, rejection is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

### **112 Second Paragraph Rejections**

The 112, second paragraph, rejection is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

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**103 Rejection**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 40-42 and 50-56 under 35 USC 103(a) as being unpatentable over John (US Patent No. 6,067,467) is MAINTAINED for reasons of record in the office action mailed 4/28/09 and those set forth below.

In summary, Applicant asserts that the cited prior art, John, does not teach the step of obtaining a second electroencephalogram from an awake patient for comparison to a first electroencephalogram. In addition, Applicant asserts that any interpretation of John that the second electroencephalogram might be from an awoken patient would result in an 'inoperable invention'.

Applicant's arguments are non-persuasive for the following reasons. The term 'awake' as defined by Merriam-Webster Online Dictionary ("awake." Merriam-Webster Online Dictionary. 2009. Merriam-Webster Online. 2 September 2009, <http://www.merriam-webster.com/dictionary/awake>), means 'to rouse from sleep', 'to become aware or cognizant', 'to rouse from a quiescent or inactive state', 'to make active' or 'to stir'. In John, a patient monitoring system is disclosed wherein an electroencephalograph (EEG) is used for patients during **and** after a medical procedure (see entire document, especially, abstract). Specially, the process involves (a) pre-operative preparation of the patient wherein initial EEG measurements are taken while the patient is awake, preferably, before the anesthesia is administered (column 4, lines 22-44). (b) In the intra-operative stage, EEG data is obtained for a patient during the

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surgical procedure (column 8, lines 17-38). (c) Next, the patient may be monitored in the recovery room/ICU using the EEG system disclosed in John. The recovery room/ICU monitoring enables the doctor to obtain a new self norm for the patient at each stage of recovery (i.e., as muscle paralysis is lessened and the patient becomes conscious). If the patient regresses, statistical data will illustrate such regression. The trajectories may be plotted against the self norms (Note that the plural of the term 'norm' indicates that multiple EEGs have been taken) of the patient being monitored for the most sensitive detection of clinically significant fluctuation within each patient, against populations norms to assess deviation from healthy persons; or against group average values constructed against some reference group of patients (column 14, lines 25-63 and columns 14-15, bridging paragraph). Thus, based on the disclosure of John, it would be obvious to a skilled practitioner in the art to take additional EEGs of an awoken patient because the reference discloses that multiple EEGs are taken of the patient. The EEGs are obtained prior to the operative procedure, during the operative procedure, and after the operative procedure (recovery room/ICU) when the subject is 'awaken'. Hence, a second EEG when a patient is 'awake' is within the scope of John. While John takes various EEGs and analyze the data such that multiple EEGs are obtained prior to the patient being 'awaken' from the anesthesia, any EEGs taken during recovery/ICU after the anesthesia wears off results in the patient being awoken from an inactive state. As a result, the method steps of the instant invention 'comprise' obtaining two EEGs, one of which is referred to as 'the second EEG taken when the patient is awoken' is within the scope of John. Furthermore, it is noted that the term 'comprise' as

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in the instant invention, allows for additional steps (i.e., obtaining various EEGs before a patient is awoken) to be present. Thus, the rejection is deemed proper.

### **WITHDRAWN CLAIMS**

3. Claims 61-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

**Notes:** It is duly noted that Applicant asserts that claims 61-64 merely represent an amendment of claim 1. In addition, it is asserted that the fundamental scope of the invention embodied by claims 61-64 have not been substantially changed such that now the Examiner faces an undue examination burden.

Applicant's arguments are non-persuasive for the following reasons. First, claim 1 has never been examined in the instant application. The claim was withdrawn from consideration from the very beginning of prosecution. Specifically, in Applicant's preliminary amendment filed 6/23/03, Applicant requested that claims 1-39 and 46-49 be withdrawn from consideration. In the office action mailed 5/25/05, page 2, first paragraph, the Examiner acknowledged the preliminary amendment and Applicant's request that the claims be withdrawn. Secondly, if Applicant is referring to claim 40 instead of claim 1, the search of claims 61-64 is of a different scope. In particular, independent claim 61 does not require a second EEG and the steps of step d (claim 61) are not required for claim 40, neither are they obvious modifications of claim 40. Thus, claims 61-64 will remain withdrawn by original presentation.

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**NEW GROUNDS OF REJECTION****Double Patenting Rejection**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 40-42 and 50-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-18, and 22-29 of U.S. Patent No. 6,622,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims involve determining the medication efficacy. The claims differ in that those of the patented invention not only determine the medication efficacy, but use such data for treating physiologic brain imbalances. Thus, it would have been obvious to a skilled artisan at the time the invention was made that both inventions disclose overlapping subject matter because (1) both inventions disclose taking multiple EEGs and analyzing the data after administering a drug/medication (see patented claim 28); (2) generating univariate Z scores (see patented claims 14-18), and (3) determining the differential change between the data obtained. Furthermore, the skilled artisan would recognize that if one determines the efficacy by administering medicines and analyzing the data, it is inherent that one is being treated for a brain abnormality as in the patented invention because the skilled artisan would recognize that in the medical field the purpose of an EEG is to generate a graphic record of the electric activity of the brain to determine the absence/presence of abnormalities.



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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/  
Primary Examiner  
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September 1, 2009